In this issue:

- HARPO’s web address has been updated
- News Distribution Lists
- Student research
- Engaged in research?
- HARPO blog

HARPO’s web address has been updated

HARPO’s web address has changed to reflect changes made to the UMBC Research site. Go to http://www.umbc.edu/research/HARPO/ to access information about the IRB, IACUC and other compliance issues.

News Distribution Lists

The Office for Human Research Protections (OHRP) and the Office of Laboratory Animal Welfare (OLAW) invites all researchers to sign up for their news distribution lists. These act a primary source of news, regulatory changes and updates from the federal perspective.


Student Research within a Faculty Advisor’s Approved Protocol

Student researchers will, at times, develop ideas for research projects as part of a senior thesis, master’s project or doctoral dissertation that involve using data collected on a faculty advisor’s IRB approved protocol. The IRB will allow this provided the level of risk does not change, no additional benefits are realized by participants, and the scope of the student’s research project does not significantly differ from the parent protocol.

Rather than burden a student researcher with completing a full application for review and approval, the IRB has developed a Thesis, Masters or Dissertation Research Notification form. This form will assist the IRB in monitoring if the planned activities of the project are already part of a previously IRB approved protocol and/or if there will be any modifications (to risks, consent processes, use of identifiers, etc.) during the course of the research project that will change the provisions of the approved protocol.

If you have a project that falls within this category, download this form (http://www.umbc.edu/irb/tmdr_application.doc) and follow the directions.

IACUC review of federal grant funded animal research

PHS Policy regarding review and approval of animal studies state that “the IACUC shall conduct continuing review of activities covered by this policy at appropriate intervals as determined by the IACUC but not less than once every three (3) years”. UMBC animal research protocols are approved for a three-year term. The investigator or instructor must resubmit a new application for Committee review in order to continue research activities.
The Office of Laboratory Animal Welfare (OLAW) recently issued guidance about this (http://grants.nih.gov/grants/olaw/faqs.htm#proto_20). If this occurs, the PHS awarding unit will not make an award unless the institution provides "...verification of approval by the IACUC of those components of the application or proposal related to the care and use of animals".

IACUC review must be performed prior to the conduct of any PHS-supported animal activity; this usually means approval must be obtained before an award is made and well before any animal research activity can begin. But, an IACUC can review activities if they will occur later in the life cycle of a grant. OLAW says that during these rare cases, the grant application must clearly explain when these activities will occur and that the PHS awarding component will issue a Notice of Award with a special term and condition indicating that no funds may be drawn from the grant or contract until a valid IACUC approval date has been issued by the IACUC.

Be sure to discuss any and all components with your OSP contact during the UMBC routing process or with the Human and Animal Research Protections Office.

**Engaged in human research**
When an institution is engaged in non-exempt human subjects research that is conducted or supported by HHS, it must satisfy HHS regulatory requirements related to holding an assurance of compliance and certifying institutional review board (IRB) review and approval.

Before engaging in human subjects research that is not exempt, an institution must hold or obtain an OHRP-approved Federalwide Assurance and certify to the HHS agency conducting or supporting the research that the research has been reviewed and approved by an IRB.

*Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. A *human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. An *institution* is defined in 45 CFR 46.102(b) as any public or private entity or agency (including federal, state, and other agencies).

In other words, institutions are considered engaged in an HHS-conducted or -supported non-exempt (EXPEDITED OR FULL BOARD) human subjects research project when the involvement of their employees or agents in that project falls into various examples. For more information, go to http://www.hhs.gov/ohrp/humansubjects/guidance/engage08.html.

**HARPO Blog**
Additional news, updates and information from the Human and Animal Research Protections Office can also be found on the [HARPO blog at http://harponotes.blogspot.com/](http://harponotes.blogspot.com/).